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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/674,914	09/30/2003	Bevil J. Hogg	5236-000452	8982

28997 7590 12/10/2008

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EXAMINER	
NGUYEN, HUONG Q	
ART UNIT	PAPER NUMBER
3736	
MAIL DATE	DELIVERY MODE
12/10/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/674,914	HOGG ET AL.	
	Examiner	Art Unit	
	HELEN NGUYEN	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 September 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1-6,8-17,38-40,51 and 52* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,8-17,38-40,51 and 52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *30 September 2003* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This Office Action is responsive to the Appeal Brief filed 9/22/2008. In light of Applicant's arguments, the finality of the previous Office Action is withdrawn and replaced with the following. As the amendments to the claims and drawing have not been entered as indicated in the attached Advisory Action, the Office action is responsive to claims filed 1/9/2008. **Claims 1-6, 8-17, 38-40, and 51-52** remain pending and under prosecution.

Drawings

2. The drawings remain objected to as failing to comply with 37 CFR 1.84(p)(5) because Applicant has failed to address that they do not include the following reference sign(s) mentioned in the description: "57" in ¶0019 and "97" in ¶0021 of p.7 of the specification. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

3. **Claims 51-52** remain objected to because Applicant has failed to address the following informalities: Claim 51 recites dependency upon cancelled claim 50. It is therefore believed that Claim 51 meant to be cancelled as well and will be treated as such in the following rejection. Applicant is requested to review said claim and determine its appropriate status and/or dependency. Claim 52 should recite "a control system…for controlling THE elongate medical device that further includes at least one magnet." It is noted that the recitation of the magnet is already previously introduced in the claim. Appropriate correction is required.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. **Claim 1-6, 8-9, 11-17, and 52** are rejected under 35 U.S.C. 103(a) as being unpatentable over Stereotaxis (WO 00/07641) in view of Osadchy et al (US Pat No. 6266551).

6. In regards to **Claim 1**, Stereotaxis discloses a medical navigation system for controlling the distal end of an elongate flexible medical device in a subject's body, the system comprising:

an elongate flexible medical device 24 having on its distal end 76 one or more magnetically responsive elements 78 that respond to an externally applied magnetic field to

change the direction of the distal end of the medical device, best seen in Figure 1-3 (p.3: 17-20; p.8: 33-37; p.9: 4-11);

a navigation device 22 configured to create a magnetic field used to steer the elongate flexible medical device, and to determine, as a function of the physical and geometric properties (p.5: 1-5; p.8: 37-39; p.9: 1-17) actuation control variables for an applied actuation consisting essentially of an external magnetic field, where the navigation device determines and applies an appropriate magnetic field direction for actuating the distal end of an elongate flexible medical device and thereby changing its orientation (p.5: 6-17, 31-38; p.6: 23-27; p.7: 6-26; p.8: 7-29);

an electronic interface 36, 38, 40 for selectively operating the navigation device for selectively controlling the orientation of the distal end of the elongate flexible medical device, the electronic interface comprising a processor in computer 26 and including at least one software program, wherein the interface provides actuation instructions to the navigation device for controlling the distal end of the device (p.4: 26-30; p.5: 6-10; p.6: 1-15, 24-40; p.7: 1-26), which instructions take into account the physical and geometric properties of the elongate medical device (p.5: 1-5; p.8: 37-39; p.9: 1-17).

7. However, Stereotaxis does not disclose an electronic identification device on the elongate medical device that includes information on the physical and geometric properties of the elongate medical device including the number of magnetically responsive elements and spacing therebetween, and identification information that provides for elongate flexible medical device identification, wherein navigation of the device is only enabled in the presence of the electronic identification device.

8. Osadchy et al disclose a catheter system comprising an electronic identification device 90 on an elongate flexible medical device 20 that includes information on the physical and geometric properties of the elongate medical device including the number of magnetically responsive elements 60, 62, 64 and spacing therebetween, i.e. d_y and d_2 (Col.11: 1-22, 26-31, 65-67; Col.12: 1-16), best seen in Figure 1-2, wherein the number of magnetically responsive elements and the spacing therebetween are used to determine calibration correction data (Col.15: 17-21, 53-58) to enable proper determination by computer 36 of the actual position and orientation of the distal tip 26 of the elongate medical device in the body (Col.15: 26-29, 64-67; Col.16: 1-13, 52-55) and wherein said unique calibration correction data for said elongate medical device is stored on the electronic identification device 90 (Col.16: 26-43). Osadchy et al also disclose an electronic interface 36 comprising a processor 40 and includes at least one software program that enables use and thus navigation control of the elongate medical device only in the presence of the electronic identification device (Col.5: 60-62; Col.17: 33-46).

9. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Stereotaxis to include an electronic identification device on the elongate medical device that includes information about the elongate medical device such as the physical and geometric properties of the elongate medical device including the number of magnetically responsive elements and spacing therebetween, and the instructions to the navigation device take into account the number of magnetically responsive elements and spacing therebetween obtained from the electronic identification device, and wherein navigation of the device is only enabled in the presence of the electronic identification device, as taught by Osadchy et al, to enable accurate determination of the position and orientation of the elongate

medical device for proper navigation by taking into account the positioning of the magnetically responsive elements, and to ensure that such pertinent identifying information is provided for each particular elongate medical device before use for improved navigation and safety.

10. In regards to **Claims 2**, Osadchy et al disclose the electronic identification device 90 includes a memory (Col.16: 37-43), and wherein the interface 36 includes a reader for reading the memory (Col.16: 52-55).

11. In regards to **Claims 3**, Osadchy et al disclose the electronic identification device 90 includes a memory unit (Col.16: 37-43) and a processing unit that communicates with the interface for transferring information (Col.7: 62-67).

12. In regard to **Claims 4-5 and 8-9**, Osadchy et al disclose the memory contains unique identifying information about the type of device, and wherein the interface includes a database of the unique identifying information of the type of devices with which the interface is intended to operate (Col.17: 33-46).

13. In regards to **Claim 6**, Osadchy et al disclose the electronic identification device 90 is a circuit, i.e. microcircuit best seen in Figure 5 that is connected to the interface 36.

14. In regards to **Claim 11**, Stereotaxis in combination with Osadchy et al disclose the interface includes a plurality of programs, each adapted for use with a different type of elongate

flexible medical device, each program operating only when an electronic identification device for the particular type of elongate flexible medical device is present (Osadchy et al Col.5: 50-62).

15. In regards to **Claim 12**, Osadchy et al disclose the electronic identification device 90 includes an integrated circuit.

16. In regards to **Claim 13**, Osadchy et al disclose the interface 36 operates on the electronic identification device 90 to prevent reuse of the elongate flexible medical device (Col.18: 46-55).

17. In regards to **Claim 14**, Osadchy et al disclose the interface 36 tracks elapsed time of use of the identified elongate flexible medical device 20 and invalidates use of the identified elongate flexible medical device when the elapsed time exceeds a pre-defined limit (Col.17: 55-65; Col.18: 46-55).

18. In regards to **Claim 15**, Osadchy et al disclose the processing unit operates on the memory unit to prevent reuse of the elongate flexible medical device (Col.18: 9-55).

19. In regards to **Claim 16**, Osadchy et al disclose the electronic identification device 90 includes memory, and wherein the interface adds to or deletes information stored on the memory to prevent reuse of the device (Col.18: 9-55).

20. In regards to **Claim 17**, Stereotaxis discloses the at least one software program controls navigation by employing a computational model of flexible device physics.

21. In regards to **Claim 52**, Stereotaxis discloses a medical navigation system for controlling the distal end of an elongate medical device in the body of the patient comprising:

an elongate flexible medical device 24 including at least one magnet 78, best seen in Figure 1-3;

a control system 22 for controlling the position and/or orientation of the distal end 76 of the elongate medical device (p.5: 6-17, 31-38; p.6: 23-27; p.7: 6-26; p.8: 7-29); wherein the control system is a magnetic navigation system for controlling the elongate medical device that includes at least one magnet and uses information on the physical and geometric properties of the elongate medical device for navigational control of the device (p. 7: 15-26; p.8: 37-39; p.9: 1-17);

an interface 36, 38, 40 for accepting inputs from the user to cause the control system to selectively change the position and/or orientation of the elongate medical device (p.4: 26-30; p.5: 6-10; p.6: 1-15, 24-40; p.7: 1-26); the interface sending instructions to the control system dependent in part upon the medical device's physical and geometric property information, wherein the physical and geometric properties of the device are used in navigational control algorithms for guiding the device (p. 7: 15-26; p.8: 37-39; p.9: 1-17).

22. However, Stereotaxis does not disclose a memory device provided on the flexible medical device that includes stored information on the physical and geometric properties of the elongate medical device such as at least a magnet dimension or a magnet type that are relevant to

navigational control of the device. Osadchy et al disclose a catheter system comprising a memory device 90 on an elongate flexible medical device 20 that includes information on the physical and geometric properties of the elongate medical device including the number of magnetically responsive elements 60, 62, 64 and magnet dimension or spacing therebetween, i.e. d_y and d_2 (Col.11: 1-22, 26-31, 65-67; Col.12: 1-16), best seen in Figure 1-2, wherein the number of magnetically responsive elements and the spacing therebetween are used to determine calibration correction data (Col.15: 17-21, 53-58) to enable proper determination by computer 36 of the actual position and orientation of the distal tip 26 of the elongate medical device in the body (Col.15: 26-29, 64-67; Col.16: 1-13, 52-55) and wherein said unique calibration correction data for said elongate medical device is stored on the memory device 90 (Col.16: 26-43).

23. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Stereotaxis to include a memory device on the flexible medical device that includes information about the medical device such as the physical and geometric properties of the elongate medical device including the number of magnetically responsive elements and magnet dimension, and the instructions to the control system are dependent in part upon the number of magnetically responsive elements and magnet dimension obtained from the memory device, as taught by Osadchy et al, to enable accurate determination of the position and orientation of the flexible medical device for proper navigation by taking into account the positioning of the magnets and thus their dimensions, and to ensure that such pertinent identifying information is provided for each particular elongate medical device before use for improved navigation and safety.

24. **Claim 10** is rejected under 35 U.S.C. 103(a) as being obvious over Stereotaxis in view of Osadchy et al, further in view of Burnside et al (US Pat No. 6237604).

25. Stereotaxis in combination with Osadchy et al in the manner above disclose the electronic identification device above that transmits a signal to the interface above but do not disclose said device is RF circuit. Burnside et al teach the use of an RF circuit to effectively transmit a signal (abst). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the circuit of Stereotaxis as modified by Osadchy et al a RF circuit as taught by Burn as an effective means for such.

26. **Claims 38-40** are rejected under 35 U.S.C. 103(a) as being unpatentable over Stereotaxis in view of Garibaldi et al (US Pat No. 6401723), further in view of Osadchy et al.

27. In regards to **Claim 38**, Stereotaxis discloses a medical navigation system for controlling the distal end of an elongate medical device in the body of the patient comprising:

an elongate flexible medical device 24, best seen in Figure 1;

a control system 22, 26 for controlling the position and/or orientation of the distal end 76 of the elongate medical device (p.5: 6-17, 31-38; p.6: 23-27; p.7: 6-26; p.8: 7-29), where the elastic property of the device are used in navigational control algorithms for guiding the device, i.e. the stiffness or elasticity of the device must be taken into account when determining the magnetic field intensity required to control the distal end of the device (p.7: 15-26; p.8: 37-39; p.9: 1-17);

an interface 36, 38, 40 for accepting inputs from the user to cause the control system to selectively change the position and/or orientation of the elongate medical device (p.4: 26-30; p.5:

6-10; p.6: 1-15, 24-40; p.7: 1-26); the interface sending instructions to the control system dependent in part upon the medical device's physical and geometric property information, including one or more cross-sectional areas of the device, and the elastic property of the device obtained from the memory device as explained above, wherein the physical and geometric properties of the device are used in navigational control algorithms for guiding the device (p.5: 1-5; p.8: 37-39; p.9: 1-17).

28. However, Stereotaxis does not disclose one or more cross sectional areas of the elongate device used in navigational control algorithms for guiding the device. Garibaldi et al teach that the cross sectional area of the coil wire of an analogous elongate medical device is directly proportional to the magnetic moment of the coil, which is then directly proportional to the magnetic torque applied to the distal end of the elongate medical device (Col.4: 36-42). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Stereotaxis such that one or more cross sectional areas of the elongate device are used in navigational control algorithms for guiding the device as taught by Garibaldi et al to effectively take into account the effect of the cross sectional area on the magnetic torque of the elongate medical device.

29. However, Stereotaxis and Garibaldi et al do not disclose a memory device provided on the flexible medical device that includes the information on the physical and geometric properties including one or more cross sectional areas of the elongate device and an elastic property of the elongate medical device that are relevant to navigational control of the device as described above. Osadchy et al disclose a catheter system comprising a memory device 90 on an elongate flexible medical device 20 that includes information on the physical and geometric

properties of the medical device, i.e. the position and orientation of distal tip 26 relative to coils 60, 62, 64 as well as information regarding the position of said coils or the gains of the coils (Col.2: 1-45, 65-66; Col.3: 1-4; Col.7: 21-29), to provide effective proper medical device identification before use (Col.17: 34-46).

30. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Stereotaxis as modified by Garibaldi et al to include a memory device provided on the flexible medical device that includes the information on the physical and geometric properties such as one or more cross sectional areas of the elongate device and an elastic property of the elongate medical device that are relevant to navigational control of the device as described above, as taught by Osadchy et al, to ensure that such pertinent identifying information is provided for each particular flexible medical device before use for improved navigation and safety.

31. In regards to **Claim 39**, Stereotaxis discloses the at least one software program controls navigation by employing a computational model of flexible device physics.

32. In regards to **Claim 40**, Stereotaxis in combination with Osadchy et al disclose the memory device includes storing unique device identification information for the elongate flexible medical device, and wherein the interface includes a database of unique device identification information and corresponding device properties, and wherein the instructions sent to the control system take into account the device properties determined from the database (Osadchy et al Col.17: 33-46).

Response to Arguments

33. Applicant's arguments filed 8/26/2008 have been fully considered but they are not persuasive. In regards to Claims 1 and 52, Applicant contends that there is no motivation to combine Osadchy et al with Stereotaxis. However, it is noted that Osadchy et al teach that determination of the actual correct position of tip is done inside the body, from which the elongate medical device is subsequently navigated to its desired location (Col.15: 64-67). Please also see other citations of Osadchy et al above. Although Applicant contends that the combination of Stereotaxis and Osadchy et al would not produce Applicant's invention, it is respectfully submitted that from said teachings of Osadchy et al, one of ordinary skill in the art would recognize the need to determine the actual position of the tip for proper navigation of the elongate medical device. It is common sense to one of ordinary skill in the art that navigation requires precise knowledge of the start point as well as the end point of any device. From there, one of ordinary skill in the art would thus be reasonably led to include such determination into the navigation device of Stereotaxis and subsequently provide actuation instructions taking into account the actually position of the tip, which is determined by the number of magnetically responsive elements and spacing therebetween and a magnet dimension as elaborated above, for reasons such as taking into account the differences in actual tip position influenced by the number of the magnetically responsive elements, spacing therebetween, and dimension. Furthermore, it is noted that Osadchy et al teach calibration data may be stored in the elongate medical device necessary as necessary for the steering of the device (Col.19: 47-50). Thus, it is believed that Osadchy et al are not only aware of the need of using various physical and

geometric properties of the elongate medical device as essential in navigating the device, but also teach the advantages of such from specific properties such as the number of the magnetically responsive elements, spacing therebetween, and dimension.

34. Applicant's arguments with respect to claims 38-40 have been considered but are moot in view of the new ground(s) of rejection above.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HELEN NGUYEN whose telephone number is (571)272-8340. The examiner can normally be reached on Monday - Friday, 9 am - 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. N./
Examiner, Art Unit 3736

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736